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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,761	MIYAZAKI ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-13 and 15-44* is/are rejected.

7)☒ Claim(s) *5 and 14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/01/02,9/20/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS of 8/03/01*.

Drawings

1. Figure 4 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g) and page 1, third full paragraph of the specification, and page 10, lines 3-4 of the specification. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The proposed drawing amendments were received on October 16, 2001. These drawing amendments are accepted.

Specification

3. The abstract should be 150 words or less. MPEP 608.01(b).

Claim Rejections - 35 USC § 112

4. Claims 3, 6, 9, 10, 13, and 15-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 3: "0.01 weight %" of what?

b) Claim 6 recites the limitation "the resin having a hydrophilic polar group" in line 2. There is insufficient antecedent basis for this limitation in the claim;

c) Claim 10, line 5: should "and" be -- or --?

d) Claims 13 and 35-44 recite the limitation "the support" in line 2 of each claim. There is insufficient antecedent basis for this limitation in the claim; and

e) Claim 15–33 recite the limitation "the reagent"; however, no reagent is positively recited in claim 1, only a desired result involving a reagent.

5. Note that dependent claims will have the deficiencies of base and intervening claims.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Mink et al. (US 6,303,081 B1). See col. 1, ll. 10-20; col. 9, ll. 8-35; and col. 13, ll. 20-25.

8. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Winarta et al. (US 6,287,451 B1). See Figure 2; col. 5, ll. 16-36; and col. 4, ln. 66 – col. 5, ln. 8.

9. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Crismore et al. (US 6,270,637 B1). See Figure 1; col. 5, ll. 7-15; col. 5, ll. 22-30; and col. 8, ll. 51-59.

10. Claims 1 and 11 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Harding et al. (US 6,261,519 B1). See Figure 2 and col. 6, ll. 45-52.

11. Claims 1, 7, 8, 21, 22, 31, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Charlton et al. (US 5,798,031). See Figure 1 and col. 5, ll. 24-34. Note that surface energy is proportional to hydrophilicity. For claims 21, 22, 31, and 32 note that the reagent layer, which is on the lower wall of the cavity, has a hydrophilic polymer (claim 5 and col. 2, ll. 58-60).

12. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Charlton et al. (US 5,759,364). See the abstract; Figure 1; claim 1; and col. 8, ll. 22-44.

13. Claims 1, 2, 4, 11, 15, 17, and 25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Oberhardt et al. (US 4,849,340). See the abstract; Figures 4 and 19; and col. 14, ll. 44-64.

14. Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Parsons et al. (EP 0321738 A2). See the abstract; page 4, lines 37-43; Figure 3.

15. Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Osaka et al. (US 4,929,330). See the abstract; Figure 1; and col. 7, ll. 53-66.

16. Claims 1, 2, 4, 12, 15, 17, 25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Diebold et al. (US 5,437,999). See the abstract; Figure 5; and col. 8, ll. 37-54. For claims 12, 17, 25, and 27 note that in addition to a surfactant coating on the cavity surfaces, the reagent layer, which is on the working electrode, has the surfactant Triton X-100 (col. 10, ll. 42-52).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 3 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mink et al. (US 6,303,081 B1).

Addressing claim 3, Mink et al. teaches a biosensor which is provided with a cavity into which a liquid sample is drawn by capillary phenomenon, and is able to analyze a component in the liquid sample by a reaction between the drawn liquid sample and a reagent, wherein the surface itself of at least a portion of side walls of the sensor, the side walls facing the cavity, has hydrophilicity. Mink et al. further teaches that the side wall of the sensor facing the cavity are made of a resin material in which a surfactant is mixed. See col. 1, ll. 10-20; col. 9, ll. 8-35; and col. 13, ll. 20-25.

Mink et al. does not mention a weight range for the surfactant; however, barring evidence to the contrary, such as unexpected results, the fractional amount of surfactant used will be largely determined by the desired hydrophilicity, as surfactant is used to change the surface tension and thus the hydrophilicity of the surfaces to which it has been added.

Addressing claim 17, Mink et al. discloses that the cavity is hydrophilic (col. 3, ll. 1-27 and col. 9, ll. 16-34).

21. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winarta et al. (US 6,287,451 B1). Winarta et al. teaches a biosensor which is provided with a cavity into which a liquid sample is drawn by capillary phenomenon, and is able to analyze a component in the liquid sample by a reaction between the drawn liquid sample and a reagent, wherein

the surface itself of at least a portion of side walls of the sensor, the side walls facing the cavity, has hydrophilicity. Winarta et al. further teaches that the side wall of the sensor facing the cavity are made of a resin material in which a surfactant is mixed. See Figure 2; col. 5, ll. 16-36; and col. 4, ln. 66 – col. 5, ln. 8.

Winarta et al. does not mention a weight range for the surfactant; however, barring evidence to the contrary, such as unexpected results, the fractional amount of surfactant used will be largely determined by the desired hydrophilicity, as surfactant is used to change the surface tension and thus the hydrophilicity of the surfaces to which it has been added.

22. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crismore et al. (US 6,270,637 B1). Crismore et al. teaches a biosensor which is provided with a cavity into which a liquid sample is drawn by capillary phenomenon, and is able to analyze a component in the liquid sample by a reaction between the drawn liquid sample and a reagent, wherein

the surface itself of at least a portion of side walls of the sensor, the side walls facing the cavity, has hydrophilicity. Crismore et al. further teaches that the side wall of the sensor facing the cavity are made of a resin material in which a surfactant is mixed. See Figure 1; col. 5, ll. 7-15; col. 5, ll. 22-30; and col. 8, ll. 51-59.

Crismore et al. does not mention a weight range for the surfactant; however, barring evidence to the contrary, such as unexpected results, the fractional amount of surfactant used will

be largely determined by the desired hydrophilicity, as surfactant is used to change the surface tension and thus the hydrophilicity of the surfaces to which it has been added.

23. Claims 3, 6, 16, 19, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oberhardt et al. (US 4,849,340).

Addressing claim 3, Oberhardt et al. teaches a biosensor which is provided with a cavity into which a liquid sample is drawn by capillary phenomenon, and is able to analyze a component in the liquid sample by a reaction between the drawn liquid sample and a reagent, wherein the surface itself of at least a portion of side walls of the sensor, the side walls facing the cavity, has hydrophilicity. Oberhardt et al. further teaches that the side wall of the sensor facing the cavity are made of a resin material in which a surfactant is mixed. See the abstract; Figure 4; and col. 14, ll. 44-64.

Oberhardt et al. does not mention a weight range for the surfactant; however, barring evidence to the contrary, such as unexpected results, the fractional amount of surfactant used will be largely determined by the desired hydrophilicity, as surfactant is used to change the surface tension and thus the hydrophilicity of the surfaces to which it has been added.

Addressing claim 6, Oberhardt et al. teaches a biosensor which is provided with a cavity into which a liquid sample is drawn by capillary phenomenon, and is able to analyze a component in the liquid sample by a reaction between the drawn liquid sample and a reagent, wherein the surface itself of at least a portion of side walls of the sensor, the side walls facing the

cavity, has hydrophilicity. Oberhardt et al. further teaches that the side wall of the sensor facing the cavity is made of a resin material in which a surfactant is mixed. See the abstract; Figure 4; and col. 14, ll. 44-64.

Oberhardt et al. does not mention a thickness range for the surfactant. Barring evidence to the contrary, such as unexpected results, the thickness of the surfactant coating will be largely determined by the desired hydrophilicity and amount of expected sample. The surfactant is used to change the surface tension and thus the hydrophilicity of the surfaces to which it has been added. The more surfactant provided the greater the hydrophilicity of the surfaces and the more sample that can be accommodated at the enhanced hydrophilicity due to the surfactant. As for the surfactant thickness being several tens of angstroms this is just a matter of scaling the amount of surfactant to the size of the sensor and the expected amount of sample. Oberhardt et al. discloses that the thickness of the reaction volume can range from 0.001 to 0.02 inches (col. 14, ll. 65-68), which is compatible with a surfactant thickness of several tens of angstroms

Addressing claims 16, 19, and 29, Oberhardt et al. discloses that all of the cavity walls may be hydrophilic (Figure 19 and col. 14, ll. 44-50).

24. Claims 3, 6, 16, 19, 26, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold et al. (US 5,437,999).

Addressing claim 3, Diebold et al. teaches a biosensor which is provided with a cavity into which a liquid sample is drawn by capillary phenomenon, and is able to analyze a

component in the liquid sample by a reaction between the drawn liquid sample and a reagent, wherein the surface itself of at least a portion of side walls of the sensor, the side walls facing the cavity, has hydrophilicity. Diebold et al. further teaches that the side wall of the sensor facing the cavity are made of a resin material in which a surfactant is mixed. See the abstract; Figure 5; and col. 8, ll. 37-54.

Diebold et al. does not mention a weight range for the surfactant; however, barring evidence to the contrary, such as unexpected results, the fractional amount of surfactant used will be largely determined by the desired hydrophilicity, as surfactant is used to change the surface tension and thus the hydrophilicity of the surfaces to which it has been added.

Addressing claim 6, Diebold et al. teaches a biosensor which is provided with a cavity into which a liquid sample is drawn by capillary phenomenon, and is able to analyze a component in the liquid sample by a reaction between the drawn liquid sample and a reagent, wherein the surface itself of at least a portion of side walls of the sensor, the side walls facing the cavity, has hydrophilicity. Diebold et al. further teaches that the side wall of the sensor facing the cavity are made of a resin material in which a surfactant is mixed. See the abstract; Figure 5; and col. 8, ll. 37-54.

Diebold et al. does not mention a thickness range for the surfactant. Barring evidence to the contrary, such as unexpected results, the thickness of the surfactant coating will be largely determined by the desired hydrophilicity and amount of expected sample. The surfactant is used to change the surface tension and thus the hydrophilicity of the surfaces to which it has been added. The more surfactant provided the greater the hydrophilicity of the surfaces and the more

sample that can be accommodated at the enhanced hydrophilicity due to the surfactant. As for the surfactant thickness being several tens of angstroms this is just a matter of scaling the amount of surfactant to the size of the sensor and the expected amount of sample. Diebold et al. discloses that a measurement can be made on only 3 μ of sample (col. 12, ll. 56-61), which is compatible with a surfactant thickness of several tens of angstroms

Addressing claims 16, 19, 26, and 29, Diebold et al. discloses that the cavity is coated with surfactant and additionally the reagent, which is on the working electrode, itself may have surfactant (col. 8, ll. 37-52 and col. 10, ll. 42-52).

25. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton et al. (US 5,759,364). Charlton et al. teaches a biosensor which is provided with a cavity into which a liquid sample is drawn by capillary phenomenon, and is able to analyze a component in the liquid sample by a reaction between the drawn liquid sample and a reagent, wherein the surface itself of at least a portion of side walls of the sensor, the side walls facing the cavity, has hydrophilicity. Charlton et al. further teaches that the side wall of the sensor facing the cavity are made of a resin material in which a surfactant is mixed. See the abstract; Figure 1; claim 1; and col. 8, ll. 22-44.

Although Charlton et al. suggests a weight range for the surfactant, no thickness range for the surfactant in mentioned. Barring evidence to the contrary, such as unexpected results, the thickness of the surfactant coating will be largely determined by the desired hydrophilicity and amount of expected sample. The surfactant is used to change the surface tension and thus the

hydrophilicity of the surfaces to which it has been added. The more surfactant provided the greater the hydrophilicity of the surfaces and the more sample that can be accommodated at the enhanced hydrophilicity due to the surfactant. As for the surfactant thickness being several tens of angstroms this is just a matter of scaling the amount of surfactant to the size of the sensor and the expected amount of sample. Charlton et al. discloses that the thickness of the entire sensor can be only 6_{μ} (col. 3, ll. 2-3), which is compatible with a surfactant thickness of several tens of angstroms

26. Claims 9, 10, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harding et al. (US 6,261,519 B1) in view of the Derwent abstract of Tateishi Electronics (JP 52139778 A).

Addressing claim 9, Harding et al. teaches a biosensor which is provided with a cavity into which a liquid sample is drawn by capillary phenomenon, and is able to analyze a component in the liquid sample by a reaction between the drawn liquid sample and a reagent, wherein the surface itself of at least a portion of side walls of the sensor, the side walls facing the cavity, has hydrophilicity. See Figure 2 and col. 6, ll. 45-52.

Harding et al. does not mention having at least a portion of the side walls facing the cavity made of a rough surface. Tateishi Electronics teaches having at least a portion of a wall in the sensing region of a sensor made of a rough surface (abstract). It would have been obvious to one with ordinary skill in the art at the time the invention was made to have at least a portion of a wall in the sensing region of a sensor made of a rough surface in the invention of Harding et al., which portion would be a portion of the cavity wall in Harding et al., because as taught by

Tateishi Electronics "the analysis can be practiced with better accuracy and better reproducibility compared with use of conventional enzyme-fixed films."

Addressing claim 10, Tateishi Electronics discloses roughening the surface portion by sand-blasting.

Addressing claims 23 and 24, in Harding et al. the reagent layer is on a hydrophilic substrate (Figure 2 and col. 6, ll. 45-52).

27. Claims 9, 10, 23, 24, 33-35, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oberhardt et al. (US 4,849,340) in view of the Derwent abstract of Tateishi Electronics (JP 52139778 A).

Addressing claim 9, Oberhardt et al. teaches a biosensor which is provided with a cavity into which a liquid sample is drawn by capillary phenomenon, and is able to analyze a component in the liquid sample by a reaction between the drawn liquid sample and a reagent, wherein the surface itself of at least a portion of side walls of the sensor, the side walls facing the cavity, has hydrophilicity. See the abstract; Figure 4; and col. 14, ll. 44-64.

Oberhardt et al. does not mention having at least a portion of the side walls facing the cavity made of a rough surface. Tateishi Electronics teaches having at least a portion of a wall in the sensing region of a sensor made of a rough surface (abstract). It would have been obvious to one with ordinary skill in the art at the time the invention was made to have at least a portion of a

wall in the sensing region of a sensor made of a rough surface in the invention of Oberhardt et al., which portion would be a portion of the cavity wall in Harding et al., because as taught by Tateishi Electronics "the analysis can be practiced with better accuracy and better reproducibility compared with use of conventional enzyme-fixed films." Applicant should note that, although not needed to meet the claim limitations, Oberhardt et al. discloses having portions of all of the side walls coated with reagent (Figure 19).

Addressing claim 10, Tateishi Electronics discloses roughening the surface portion by sand-blasting.

Addressing claims 23 and 24, in Oberhardt et al. portions of all of the cavity side walls on which the reagent is located are hydrophobic (Figure 19 and col. 14, ll. 44-64).

Addressing claims 33 and 34, in Oberhardt et al. portions of all of the cavity side walls on which the reagent is located are hydrophobic (Figure 19 and col. 14, ll. 44-64) and electrochemical embodiments in which electrodes are located on a cavity wall are disclosed (col. 25, ln. 54 – col. 26, ln. 19).

Addressing claim 35, Oberhardt et al. teaches a biosensor which is provided with a cavity into which a liquid sample is drawn by capillary phenomenon, and is able to analyze a component in the liquid sample by a reaction between the drawn liquid sample and a reagent, wherein the surface itself of at least a portion of side walls of the sensor, the side walls facing the cavity, has hydrophilicity. Oberhardt et al. further teaches that the side wall of the sensor facing

the cavity is made of a resin material in which a surfactant is mixed. See the abstract; Figure 4; and col. 14, ll. 44-64.

Oberhardt et al. does not mention having at least a portion of the side walls facing the cavity made of a rough surface. Tateishi Electronics teaches having at least a portion of a wall in the sensing region of a sensor made of a rough surface (abstract). It would have been obvious to one with ordinary skill in the art at the time the invention was made to have at least a portion of a wall in the sensing region of a sensor made of a rough surface in the invention of Oberhardt et al., which portion would be a portion of the cavity wall in Harding et al., because as taught by Tateishi Electronics "the analysis can be practiced with better accuracy and better reproducibility compared with use of conventional enzyme-fixed films." As for the level of the roughness being from 0.001 μm to 1 μm, barring evidence to the contrary, such as unexpected results, this is just a matter of optimizing the roughness to best adhere the material that is to be applied to the roughed area. Applicant should note that, although not needed to meet the claim limitations, Oberhardt et al. discloses having portions of all of the side walls coated with reagent (Figure 19).

Addressing claims 43 and 44, as for the level of the roughness being from 0.001 μm to 1 μm, barring evidence to the contrary, such as unexpected results, this is just a matter of optimizing the roughness to best adhere the material that is to be applied to the roughed area.

28. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oberhardt et al. (US 4,849,340) as applied to claims 3, 6, 16, 19, and 29 above, and further in view of the Derwent abstract of Tateishi Electronics (JP 52139778 A). Oberhardt et al. does not mention having at least a portion of the side walls facing the cavity made of a rough surface. Tateishi Electronics teaches having at least a portion of a wall in the sensing region of a sensor made of a rough surface (abstract). It would have been obvious to one with ordinary skill in the art at the time the invention was made to have at least a portion of a wall in the sensing region of a sensor made of a rough surface in the invention of Oberhardt et al., which portion would be a portion of the cavity wall in Harding et al., because as taught by Tateishi Electronics "the analysis can be practiced with better accuracy and better reproducibility compared with use of conventional enzyme-fixed films." As for the level of the roughness being from 0.001 μm to 1 μm, barring evidence to the contrary, such as unexpected results, this is just a matter of optimizing the roughness to best adhere the material that is to be applied to the roughed area. Applicant should note that, although not needed to meet the claim limitations, Oberhardt et al. discloses having portions of all of the side walls coated with reagent (Figure 19).

Allowable Subject Matter

29. Claims 5 and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

30. Claim 13, 18, 20, 28, 30, 36-38, and 40-42 would be allowable if rewritten to overcome the rejection under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

31. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 5 requires the side walls of the sensor facing the cavity to be made of a film which is covered with a resin having a hydrophilic polar group. In Osaka et al. the film itself is a resin selected for its hydrophilic property (col. 7, ll. 60-66), so it would not have been obvious to covered the portion of the film exposed to the cavity with a hydrophilic resin;

b) Claims 13, 36, and 37 requires that surface of the support (presumably the surface of the electrode support) has a roughness of 0.001 μm to 1 μm. The Derwent abstract of Katayama et al. (JP 59-57156 A) teaches roughening the surface of the electrode so that a membrane can better adhere to the electrode surface. In light of Katayama et al., it would not have been obvious to roughen the surface of the substrate of Diebold et al., which was applied in the rejections of claims 12, 26, and 27, because, firstly, Katayama does not roughen the electrode substrate, but the upper electrode surface, and, secondly, in Diebold et al. the electrodes are formed on the substrate; that is, the substrate must exist before the electrodes so that the electrodes can be formed by some deposition process, such as photolithography, on the substrate. In Katayama et al. the electrode must exist before the membrane. The electrode is roughened so that when the membrane polymer

solution dries the membrane will adhere in the various crevices and undulations in the roughened electrode surface;

c) Claims 14, 18, 20, 28, 30, 38, and 40 depend directly or indirectly from allowable claim 5; and

d) Claims 41 and 42 requires that surface of the support (presumably the surface of the electrode support) has a roughness of 0.001 μm to 1 μm. The Derwent abstract of Katayama et al. (JP 59-57156 A) teaches roughening the surface of the electrode so that a membrane can better adhere to the electrode surface. In light of Katayama et al., it would not have been obvious to roughen the surface of the substrate of Charlton et al. '031, which was applied in the rejection of claim 31, because, firstly, Katayama does not roughen the electrode substrate, but the upper electrode surface, and, secondly, in Charlton et al. '031 the electrodes are formed on the substrate; that is, the substrate must exist before the electrodes so that the electrodes can be formed by some deposition process, such as printing, on the substrate. In Katayama et al. the electrode must exist before the membrane. The electrode is roughened so that when the membrane polymer solution dries the membrane will adhere in the various crevices and undulations in the roughened electrode surface.

Information Disclosure Statement

32. The information disclosure statement filed August 03, 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The following foreign patents have not been received

AU 6378398,

AZ 9803200, and

NO 981684.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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03/19/04
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